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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/721,582

11/25/2003

Joseph F. Obermiller

PA-5213-CIP-CON

5774

48004

7590

04/23/2008

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EXAMINER

BLANCO, JAVIER G

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/721,582	Applicant(s) OBERMILLER, JOSEPH F.	
	Examiner JAVIER G. BLANCO	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 31, 2007; February 13, 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 11 and 14-28 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 11 and 14-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7, and 18-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on **October 31, 2007** has been entered.

Response to Amendment

2. Applicant's amendment of claims 1, 7, 14, 15, and 17-23 in the reply filed on **February 13, 2008** is acknowledged.
3. Applicant's addition of claims 26-28 in the reply filed on **February 13, 2008** is acknowledged.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Regarding claim 28, the limitation “the inner edge defining an opening to restrict blood flow” is indefinite as to the scope of the invention. An “opening” by definition can’t “restrict” flow (i.e., since it is open).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 7, 18-24, 26, and 28 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by DiMatteo et al. (US 6,440,164 B1).

Referring to Figures 1-4, 14-16, and 24A-26B, DiMatteo et al. disclose an expandable implantable vascular valve comprising:

(i) A support frame (trellis 24 includes scaffold 30 and leaf frames 62; trellis 224 includes scaffold 230 and leaf frame 232);

(ii) One or more leaflets (e.g., valve leaf cover 80) comprised of a biomaterial (see list of materials disclosed in columns 10 and 11) attached to the support frame and *configured to function* (emphasis added to functional language) as a valve; and

(iii) Wherein the biomaterial is wrapped around the support frame and affixed to itself by heat setting, adhesive welding, application of uniform force (= pressure), and other bonding

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techniques (see column 11, lines 27-32), thereby securing the one or more leaflets to the support frame (see entire document). As it is already well known in the art, the process of manufacturing/preparing remodelable material (e.g., pericardial tissue, etc.) will render said material hydrated and ready to be used (e.g., the material is then easier to mold, stretch, conform, etc.). First liner 82 could be laminated with second liner 88, therefore encasing all of trellis 24 or just scaffold 30 (see column 11, lines 21-27 and lines 32-35). An "overhang portion" or "skirt portion" can be broadly interpreted as the portion that will "overhang" before liner 80 (or liner 82) is attached/laminated to itself. When the valve is in the open position, an outer edge (e.g., the tip of the leaflets) of said leaflets will engage the vessel wall. Another example of an outer edge is shown in Figures 1 and 3, wherein the line denoted by character 22 shows a portion of said leaflets in contact with the vessel wall. Figures 24A-26B clearly show the body of the one or more leaflets (e.g., leaflets 240, 241) as traversing the support frame (trellis 224 and/or leaf valve frame 232) from the outer edge to the inner edge.

As shown in Figure 15 (and disclosed at column 11, lines 15-20), liner 82 could comprise at least one flap/extension/overhang/excess/skirt 86 extending beyond the frame, and folded over the frame and affixed to itself (see column 11, lines 15-20 and lines 32-35). As shown in Figure 16 (and disclosed at column 11, lines 9-15), liner 82 could comprise at least one flap/extension/overhang/excess/skirt 84 extending beyond the frame. As shown in Figure 8 (and disclosed at column 12, lines 44-56), liner 82 comprises flap/extension/overhang/excess/skirt 80a, which is folded over the frame and affixed/laminated to itself. As shown in Figures 24A-26B (and disclosed at column 16, line 54 to column 17, line 27), liner 280 comprises excess material (e.g., "overhang") that will assume/form a concave shape (e.g., a "pocket") *adapted to*

capture retrograde fluid flow (see column 17, lines 8-12). Said overhang/skirt portion is formed after the liner/covering is folded over the frame and affixed/laminated to itself. Said “pocket” is directly or indirectly attached to an outside edge (e.g., edge wrapped/folded over the support frame) of the one or more leaflets.

8. Claims 1, 7, 18-26, and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Duran (US 5,489,297).

Referring to Figures 16 and 17, Duran discloses a valve comprising:

- (i)** A frame (stent 110) having two or more sides (a strut/leg may have an anterior side, a posterior side, and two lateral sides), the frame formed into two or more legs (each one of the three commissure supports 146 comprises at least two legs) and comprising a bioabsorbable material (e.g., polyglycolic acid, polylactic acid, polyethylenes, polyhydroxybutyrate, collagen, soluble sugars, etc; see column 11, lines 45-67);
- (ii)** A covering (membrane 112) attached to at least two sides (e.g., wrapped/folded around the strut/leg) of a first leg, a second leg, and a third leg *to form* (emphasis added to functional language) the body of a first leaflet, a second leaflet, and a third leaflet, the covering comprising a material with remodeling properties (e.g., pericardium, pleura, peritoneum, fascia lata, or other biological membrane sources; see column 12);
- (iii)** Each leaflet having an inner body edge and an outer body edge (see Figures);
- (iv)** Wherein each of the inner body edges comprises a flexible free edge (e.g., free edges 117) that defines a portion of the valve orifice; and wherein the body of the one or more leaflets traverses the support frame from the outer edge to the inner edge; and

(v) Wherein the frame is flexible, and is *moveable* (capable of being moved) between a deployed configuration and a compressed delivery configuration.

The “overhang portion” or “skirt portion”, as broadly claimed, is broadly interpreted as the portion that will “overhang” before attaching/laminating to itself. Alternatively, when the valve prosthesis is assembled (e.g., the biomaterial is attached to the support frame) each leaflet body (e.g., from the outer edge to free edge 117) defines an “overhang portion” that will assume/form a concave shape (e.g., a “pocket”) during retrograde fluid flow (see Figure 16C to Figure 16E).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiMatteo et al. (US 6,440,164 B1).

DiMatteo et al. disclose the invention as claimed (see 102(e) rejection) except for particularly disclosing the specific materials disclosed in claim 25 and claim 27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the specific materials disclosed in claim 25 and claim 27 with the valve of **DiMatteo et al. ‘164**, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duran (US 5,489,297).

Duran discloses the invention as claimed (see 102(b) rejection) except for particularly disclosing the specific materials disclosed in claim 27. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the specific materials disclosed in claim 27 with the valve of **Duran '297**, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

12. With regards to the 102(e) rejection based on DiMatteo et al. (US 6,440,164 B1), Applicant's arguments filed in the Amendment/Response filed **February 13, 2008** have been fully considered but they are not persuasive. The Applicant argues: "*DiMatteo does not teach or suggest an overhang portion in the implantable valve prosthesis after attaching a biomaterial to a support frame*". The Examiner respectfully disagrees.

a. As shown in Figure 15 (and disclosed at column 11, lines 15-20), liner 82 could comprise at least one flap/extension/overhang/excess/skirt 86 extending beyond the frame, and folded over the frame and affixed to itself (see column 11, lines 15-20 and lines 32-35). As shown in Figure 16 (and disclosed at column 11, lines 9-15), liner 82 could comprise at least one flap/extension/overhang/excess/skirt 84 extending beyond the frame. As shown in Figure 8 (and

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disclosed at column 12, lines 44-56), liner 82 comprises flap/extension/overhang/excess/skirt 80a, which is folded over the frame and affixed/laminated to itself.

b. As shown in Figures 24A-26B (and disclosed at column 16, line 54 to column 17, line 27), liner 280 comprises excess material (e.g., "overhang") that will assume/form a concave shape (e.g., a "pocket") *adapted to capture* retrograde fluid flow (see column 17, lines 8-12). Said overhang/skirt portion is formed after the liner/covering is folded over the frame and affixed/laminated to itself. Said "pocket" is directly or indirectly attached to an outside edge (e.g., edge wrapped/folded over the support frame) of the one or more leaflets.

13. With regards to the 102(b) rejection based on Duran (US 5,489,297), Applicant's arguments filed in the Amendment/Response filed **February 13, 2008** have been fully considered but they are not persuasive.

The Applicant argues: "*Duran does not teach or suggest an overhang portion in the implantable valve prosthesis after attaching a biomaterial to a support frame*". The Examiner respectfully disagrees. When the valve prosthesis is assembled (e.g., the biomaterial is attached to the support frame) each leaflet body (e.g., from the outer edge to free edge 117) defines an "overhang portion" that will assume/form a concave shape (e.g., a "pocket") during retrograde fluid flow (see Figure 16C to Figure 16E).

Conclusion

14. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art

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of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

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/Javier G. Blanco/

Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738